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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,605	09/29/1998	TOM DE VRINGER	98.554	8895

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/155,605	<b>Applicant(s)</b> DE VRINGER ET AL.	
	<b>Examiner</b> Gollamudi S Kishore, PhD	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 19-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The response filed on 4-12-04 is acknowledged.

Claims included in the prosecution are 1-17 and 19-37.

#### *Claim Rejections - 35 U.S.C. § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-17 and 19-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 521 562 in view of EP 0 678 295, EP 0159237, GB 2002319, JP 05194253 by themselves or in combination.

EP 0521 562 teaches instant reverse vesicles containing sucrose fatty acid esters (note the abstract, Examples and claims). What this reference lacks is the teachings of dehydration of these vesicles to obtain a powder.

EP 0678 295 teaches that vesicular preparations can be lyophilized to form powders (note Example 1 and claims 1 and 7).

EP 0159237 teaches that emulsions (micelles) can be freeze-dried to form powders, which are easier to handle than emulsions (note the abstract).

GB teaches that dehydration of lipid vesicles (liposomes) to prepare a stable powder, which can be stored for longer periods of time (note the abstract).

JP 05194253 teaches the preparation of a powder of reverse micelles containing a surfactant (note the abstract).

The removal of solvent from the vesicles of EP 562 to form powders would have been obvious to one of ordinary skill in the art since EP 295, 237 and GB each teach that vesicular preparations can be dehydrated and because of the advantages of powders compared to liquids taught by EP 237 and GB; one skilled in the art would be motivated to dehydrate the vesicles of EP 562 with the expectation of obtaining similar powders. One of ordinary skill in the art would be motivated further to dehydrate the reverse micelles containing surfactants to prepare a powder since JP (253) teaches that powders of reverse micelles can be prepared.

Applicant's arguments once again are based on the amendment adding the limitation that when the powder when dispersed in a biodegradable oil and the percent yield of the reversed vesicles is greater than when the same amount of reversed vesicles is prepared directly in the biodegradable oil. These arguments are not found to be persuasive since previously pointed out, the prior art does not suggest the use of biodegradable oil in the preparation of vesicles. A careful examination of EP (562) indicates the use of a synthetic oil just as in instant application. Therefore, it is unclear as to how this limitation would overcome the rejection based on EP reference and how

the findings are considered as unexpected. In response, applicant states, "The office appears to argue that applicant's evidence of unexpected properties is of no consequence because the prior art does not suggest the use of biodegradable oils in the preparation of vesicles" (page 2 of the response). Applicant misunderstood the examiner's position. The examiner did not question the presumed unexpected nature of the results. The examiner was pointing that EP 562 does not teach the use of oil during the preparation of the vesicles and therefore, one would expect the same nature of results as obtained by applicant when subjected to further treatment whether those results are unexpected or not. Applicant's arguments that contrary to the office's assertion, teaches a number of biodegradable oils that can be use for the preparation of dispersions (not powders) of reversed vesicles are not found to be persuasive since EP in examples (example 1) clearly teaches the use of synthetic oils such as mineral oil (liquid paraffin). Applicant's arguments that it is the powder (and method of making it) and not the dispersion that possesses the unexpected properties therefore are not found to be persuasive.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gollamudi S Kishore, PhD  
Primary Examiner  
Art Unit 1615